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10/764,415	01/23/2004	Mark William Bodmer	674525-2009	8348

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EXAMINER

BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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07/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/764,415

Applicant(s)

BODMER ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 15-17, 24, 25 and 50-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-23, 26-49, 83 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/27/04; 1/23/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-49 and 83-84, directed to a method of detecting modulators of Notch or immune signaling in the reply filed on 11 April 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's election of the following species in the replies filed on 11 April 2007 and 18 April 2007 is also acknowledged: endogenous target gene of Notch signaling, TCR signaling pathway, B7.1-CD80, and activating Notch.

Claims 15-17, 24-25, and 50-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11 April 2007.

Claims 1-14, 18-23, 26-49, and 83-84 are under consideration in the instant application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

1. The disclosure is objected to because of the following informalities:
 - 1a. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 33, line 25). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

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1b. The Brief Description of the Drawings for Figures 4-30 at page 15 of the specification is not descriptive. For example, the specification simply states “Figure 8 shows the results of Example 4”. However, according to MPEP § 608.01(f) and CFR 1.74, when there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals.

1c. The Brief Description of the Drawings for Figure 30 indicates that there are two views, “30A” and “30B”. However, there are no such views labeled on Figure 30. (Please note that this issue could be overcome, for example, by amending the specification to refer Figure 30 only and then to reference Experiment 1 and Experiment 2 in the Brief Description.)

Appropriate correction is required.

Claim Objections

2. Claims 19, 37, 38, 42, and 45 are objected to because of the following informalities:

2a. Claim 37 is missing a period at the end of line 2.

2b. Claim 42 is missing a period at the end of line 1.

2c. In claim 45, line 2, the first recitation of “and” should be deleted (i.e., “antibody or and an...”).

2d. Claim 19 uses the acronyms “CBF-1”, “Hes-1”, “Hes-5”, “E(spl)”, “IL-10”, “Dlx-1”, “CTLA4”, without first defining what it represents in the independent claims. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

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2e. Claims 37-38 use the acronym "TCR" without first defining what it represents in the independent claims. While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 32-33 and 83-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 32-33 and 83-84 are rejected as being indefinite because it is not clear (1) what unit of weight the claims are referring to and (2) what method by which the molecular weight is calculated the claims are referring to. (For example, a 500 kD protein separated by SDS-PAGE may not have the same molecular weight if separated via a different method (i.e., 2D gel)).

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-14, 18-23, 26-49, and 83-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims of the instant application are directed to, for example, a method for detecting modulators of Notch or immune signalling comprising the step of (in any order): (a) activating Notch signaling in a cell of the immune system; (b) contacting the cell with a candidate modulator of Notch or immune signaling; (c) monitoring Notch or immune signaling; (d) determining whether the candidate modulator modulates Notch or immune signaling. Claim 13 recites that monitoring Notch signaling comprises monitoring expression levels of at least one target gene. Claim 20 recites the target gene is under the transcriptional control of a promoter region sensitive to i) Notch signaling; and ii) a second signal. Claim 21 recites that the promoter region is sensitive to iii) a third signal.

The claims do not require that Notch signaling, immune signaling, second signal, or third signal possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing features. Thus, the claims are drawn to a genus of Notch signaling components/pathways, immune signaling components/pathways, second signals, and third signals.

The specification of the instant application discloses teaches that “the expression “Notch signalling” is synonymous with the expression “the Notch signalling pathway” and refers to any one or more of the upstream or downstream events that result in, or from, (and including) activation of the Notch receptor” (page 16, lines 26-29). The specification also discloses that signal transduction from the Notch receptor can occur via different pathways (page 19, line 9). The specification teaches that “Notch signalling means specific signalling, meaning that the

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signal detected results substantially or at least predominantly from the Notch signalling pathway, and preferably from Notch/Notch ligand interaction, rather than any other significant interfering or competing cause, such as cytokine signalling. In one embodiment the term "Notch signalling" excludes cytokine signaling" (page 22, lines 16-21). Furthermore, the specification teaches that "[t]he term "immune signalling" as used herein includes any signalling pathway for activation of cells of the immune system, preferably leukocytes, more preferably lymphocytes, and more preferably T-cells. Preferably immune signalling relates to a signalling pathway activated by activation of the T-cell receptor, B-cell receptor or a Toll-like receptor" (page 68, lines 23-27).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, there is not even identification of any particular structure or function that must be conserved. The specification of the instant application does not teach any specific Notch signaling, immune signaling, second signals, or third signals. The brief description in the specification is not adequate written description of an entire genus of Notch signaling components/pathways, immune signaling components/pathways, second signals, and third signals encompassed by the claimed methods.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (See page 1117). The specification does not "clearly allow persons of

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ordinary skill in the art to recognize that [he or she] invented what is claimed” (See *Vas-Cath* at page 1116).

The skilled artisan cannot envision the Notch signaling, immune signaling, second signal, or third signal of the encompassed methods, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The Notch signaling, immune signaling, second signal, and third signal are required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.

Therefore, only a specific (1) Notch signaling component/pathway, (2) immune signaling component/pathway, (3) second signal, and (4) third signal, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

8. Claims 1-14, 18-23, 26-49, and 83-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **(I)** a method for detecting modulators of Notch signal transduction comprising (a) activating T cells; (b) activating Notch on the T cells with the Notch ligand, Delta; (c) contacting the T cells with a candidate modulator; (d)

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monitoring the levels of one or more cytokines produced by the activated T cells, wherein the cytokines are selected from the group comprising IL-10, IL-13, and IFN γ ; and (e) detecting a change in the level of one or more cytokines in the presence of the candidate modulator as compared to the cytokine level in the absence of the modulator, wherein a change in the level of one or more cytokines produced indicates the candidate modulator alters Notch signal transduction, *does not reasonably provide enablement for* methods for detecting modulators of Notch or immune signalling comprising the step of (in any order): (a) activating Notch signaling in a cell of the immune system; (b) contacting the cell with a candidate modulator of Notch or immune signaling; (c) monitoring Notch or immune signaling; (d) determining whether the candidate modulator modulates Notch or immune signaling. It is also noted that the specification is not enabling for all the claims that are variations from the steps listed above (for example, see claims 2-6, and 83). The specification is also enabling for **(II)** a method for detecting modulators of Notch signal transduction comprising (a) activating T cells; (b) activating Notch on the T cells with the Notch ligand, Delta-1; (c) contacting the T cells with a candidate modulator; (d) monitoring the expression level of *Hes-1*; and (e) detecting a change in the level of *Hes-1* in the presence of the candidate modulator as compared to the level of *Hes-1* in the absence of the modulator, wherein a change in the level of *Hes-1* indicates the candidate modulator alters Notch signal transduction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims of the instant application are directed to, for example, a method for detecting modulators of Notch or immune signalling comprising the step of (in any order): (a) activating

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Notch signaling in a cell of the immune system; (b) contacting the cell with a candidate modulator of Notch or immune signaling; (c) monitoring Notch or immune signaling; (d) determining whether the candidate modulator modulates Notch or immune signaling. Claim 13 recites that monitoring Notch signaling comprises monitoring expression levels of at least one target gene. Claim 20 recites the target gene is under the transcriptional control of a promoter region sensitive to i) Notch signaling; and ii) a second signal. Claim 21 recites that the promoter region is sensitive to iii) a third signal. Claim 83 recites a method for identifying a modulator of Notch signaling comprising the steps of (a) monitoring Notch signaling in a cell of the immune system in the presence and absence of a candidate modulator having a molecular weight of less than about 1000 and (b) determining whether the candidate modulator modulates Notch signaling, thereby identifying a modulator of Notch signaling.

In Example 4 of the instant application, the specification teaches that stimulated CD4⁺ T cells are cultured with mouse Delta 1 extracellular domain (Notch ligand) and then harvested (page 104). Using RT-PCR, the expression level of mHes-1 was evaluated for cells cultured with and without Delta (bottom of page 104 through the top of page 105; Figure 8). The specification teaches that M450 Streptavidin Dynabeads are coated with anti-hamster IgG1 biotinylated monoclonal antibody, anti-human IgG4 monoclonal antibody, or both antibodies. The anti-hamster IgG1 beads are further incubated with anti-CD3 ϵ chain monoclonal antibody, the anti-human-IgG4 beads are further incubated with Fc-Delta, and the double coated beads are incubated with both, anti-human IgG4 monoclonal antibody, or both anti-CD3 ϵ chain monoclonal antibody and Fc-Delta (page 113, lines 14-22). T cell assays are carried out with CD4⁺ T cells and the Streptavidin-coated Dynabeads, supernatants are removed, and cytokines

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measured by ELISA (page 113, lines 24-26; Figure 13). Furthermore, the specification discloses that human CD4⁺ T cells are stimulated to produce cytokines with anti-CD3/CD28 T cell expander beads, plate bound anti-CD3, or soluble anti-CD28 (page 114, lines 4-13). Beads coated with mouse Delta1EC domain-hIgG4 fusion protein are also added to the cell wells (page 114, lines 13-17). Supernatants are removed and cytokine production is measured by ELISA (page 114, lines 17-23; Figures 14-18). Additionally, the specification teaches that there is an increased number of genes showing expression in Jurkat cells in response to Delta activation in combination with anti-CD3/CD28 activation but not Delta activation alone (page 120, lines 9-18; Figures 24,26). In Example 16, the specification teaches luciferase assays with Jurkat cells with or without plate-bound hDLL1-Fc and with or without PMA/ionomycin (bottom of page 120 through page 121; Figures 27-29).

Furthermore, the specification of the instant application discloses teaches that “the expression “Notch signalling” is synonymous with the expression “the Notch signalling pathway” and refers to any one or more of the upstream or downstream events that result in, or from, (and including) activation of the Notch receptor” (page 16, lines 26-29). The specification teaches that “[t]he term “immune signalling” as used herein includes any signalling pathway for activation of cells of the immune system, preferably leukocytes, more preferably lymphocytes, and more preferably T-cells. Preferably immune signalling relates to a signalling pathway activated by activation of the T-cell receptor, B-cell receptor or a Toll-like receptor” (page 68, lines 23-27).

However, the specification of the instant application does not teach activating all possible components or pathways of Notch signaling or all possible components or pathways of immune

signaling and undue experimentation would be required of the skilled artisan to do such. The state of the art at the time the invention was made indicates that Notch signaling involves several putative pathways and is incompletely understood (Zlobin et al. Curr Pharmaceut Biotech 1: 83-106, 2000; page 86, column 1, 1st line of section (c)). Additionally, the specification does not disclose activating any other cells of the immune system other than T cells. The specification also does not monitor the expression levels of any gene target other than *Hes-1*. Post-filing date evidence states that “[a] major challenge is identifying the spectrum of Notch responsive genes, and determining when their expression reflects Notch activity” (Maillard et al. Immunol 19: 781-791, 2003; page 781, column 2, 3rd paragraph).

Furthermore, as indicated above, the specification teaches the activation of Notch on CD4+ T cells with the Notch ligand, Delta-1. In *Drosophila*, Notch ligands, Delta and Serrate, have different expression patterns, produce different mutant phenotypes, and seem to regulate different developmental decisions via activation of a single Notch receptor (Weinmaster, G. Mol Cell Neurosci 9: 91-102, 1997; page 92, column 2, 2nd paragraph). In mammals, the Notch ligand proteins (Delta, Delta-like-1, -3, and -4, and Jagged-1 and -2) have extracellular domains containing multiple EGF-repeats as well as a characteristic cysteine-rich region referred to as the Delta-Serrate-Lag-2 (DSL) domain (McKenzie et al. Sem Cell Dev Biol 14: 127-134, 2003; page 128, column 1, 1st paragraph). The DSL domain and EGF repeats are conserved between all the Notch ligands, but the Jagged proteins contain a distinct cysteine-rich region immediately proximal to the transmembrane pass (McKenzie et al., page 128, column 1, 1st paragraph). McKenzie et al. state that since this feature is not present in the Deltas, this suggests distinct biological functions for the Jagged and Delta family (McKenzie et al., page 128, column 1, 1st

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paragraph). Importantly, McKenzie et al. point out that “in mammalian systems, little is known about the extent to which different Notch ligands activate different receptors under physiological conditions, and whether there are distinct downstream signaling events triggered by different ligand/receptor combinations” (page 128, column 1, 1st paragraph). Thus, one skilled in the art would not be able to predict that all mechanisms of activating Notch signaling on all possible cells would result in the same signaling events for monitoring, as required by the instant claims. A large quantity of experimentation would be required of the skilled artisan identify a specific component/element of Notch or immune signaling to monitor, in addition to the experimentation necessary for activating any immune system cell and activating Notch signaling on the cell. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Due to the large quantity of experimentation necessary to (1) activate all possible components or pathways of Notch signaling or all possible components or pathways of immune signaling and (2) identify and monitor a specific component/element of Notch or immune signaling; the lack of direction/guidance presented in the specification regarding the same; the absence of working examples directed to the same; the complex nature of the invention; and the breadth of the claims which fail to recite limitations for Notch signaling, immune signaling, and

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how each are monitored, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-2, 4-5, 7-9, 12, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Gehring et al. (WO 200103743; published on 18 January 2001).

Gehring et al. teach a method of screening for agonists and antagonists of Notch pathway function comprising contacting the cell with an agonist or antagonist of the cell fate control gene pathway function and concurrently treating the cell with a test agonist or antagonist of the Notch pathway function; subjecting the cell to conditions that allow cell fate determination to occur; and examining the cell for an alteration of cell fate (page 51, lines 19-24). Gehring et al. further state that in order to identify a test compound as agonist or antagonist of Notch pathway function, the alteration in cell fate elicited by the test compound has to differ from the cell fate determination elicited by the method in the absence of an alteration in cell fate control gene pathway function (page 51, lines 24-28). Thus, these teachings meet the limitations of claims 1-2, 4-5, 7-9, and 31 of the instant application. Gehring et al. disclose that cells in which cell fate is altered are called “precursor cells” and can be primary cells or cell lines from any species (page 52, lines 10-13). Gehring et al. also teach that Notch pathway agonists and antagonists

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include nucleic acids, antibodies, a peptidomimetic or peptide analog, or organic molecule (page 38, line 36 through page 39, lines 1-5; page 43, lines 14-19; page 44, especially lines 24-35).

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Conclusion

No claim is allowable.

The art made of record and not relied upon is considered pertinent to applicant's disclosure:

Anderson et al. Curr Opin Genetics Develop 11:554-560, 2001 (review of Notch signaling in T cell development).

Verheyen et al. Genetics. 144(3):1127-1141, 1996 (mutagenesis screen to isolate enhancers and suppressors of the Drosophila eye phenotype caused by expression of activated Notch molecules).

Jarriault et al. Mol Cell Biol. 18(12):7423-7431, 1998 (Delta (like)-1 activates the Notch-1 cascade; Delta (like)-1 induces *HES-1* transactivation).

Artavanis-Tsakonas et al. U.S. Patent 5,780,300 (methods of Notch activation)

Artavanis-Tsakonas et al. U.S. Patent 6,436,650 (methods of screening for Notch modulators; columns 13-18, for example)

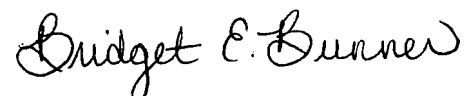
Lamb et al. US 2004/0005631 (methods of detecting modulation of Notch signaling)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
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05 July 2007



**BRIDGET BUNNER
PATENT EXAMINER**